UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

Dean Langford and Nancy Langford, husband and wife,

Plaintiffs,

v.

Zimmer, Inc. and Zimmer Holdings, Inc.,

Defendants.

Case No: 03-12245-RCL

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR RECONSIDERATION OR IN THE ALTERNATIVE FOR CERTIFICATION PURSUANT TO 28 U.S.C. § 1292(b)

ORAL ARGUMENT REQUESTED

INTRODUCTION

Plaintiffs respectfully request that this Court reconsider its September 6, 2004 Order denying Plaintiffs' Motion to Amend their Complaint. In the alternative, Plaintiffs respectfully move the Court for an order pursuant to 28 U.S.C. § 1292(b) certifying this Court's September 6, 2004 Order for interlocutory appeal.[1]

The decisions cited by Defendants relating to preemption, including *Talbott v. C.R. Bard*, were no longer good law after the United States Supreme Court's decision in *Medtronic v. Lohr* to the extent they call for complete preemption of statutory or common law claims relating to medical devices. It is clear from *Medtronic* and subsequent decisions of the District Court of Massachusetts that preemption under the MDA will not normally apply to statutory or common law claims made against manufacturers of medical devices, such as the hip implant at issue. Instead, preemption may only be found where the party claiming preemption proves that a particular state requirement interferes with a specific federal interest. Defendants have made no such showing here, and therefore Plaintiffs request that their Motion to Amend their Complaint

[1] In accordance with Local Rule 7.1, Plaintiffs have discussed the bringing of this Motion with Defendants. See Affidavit of Elizabeth A. Maki ¶ 1.

be granted. In the alternative, in light of the controlling precedent directly adverse to the authority cited by Defendants and subsequently relied upon by this Court in its September 6 Order, and in light of the substantial delay and duplication that would result were this case to proceed without a decision on this controlling issue, Plaintiffs respectfully move this Court for an order pursuant to 28 U.S.C. § 1292(b) certifying its September 6, 2004 Order for interlocutory appeal.

FACTUAL BACKGROUND

As Plaintiffs discussed in their Motion to Amend and their Reply, there are references within Mr. Langford's medical files to potential problems with other Zimmer products used in Mr. Langford's hip replacement, as well as to loosening of Mr. Langford's Centralign implant before the implant was replaced. Before adding claims relating to the devices other than the Centralign and the premature loosening, Plaintiffs wished to conduct further discovery to gain additional facts regarding these other devices. In accordance with this intent, Plaintiffs' counsel suggested that the date for amendment of the pleadings fall at the close of discovery. Defendants suggested an early date. This Court selected a date for amendment of the pleadings at the outset of discovery. In that way, the parties would be able to conduct discovery, having each parties' claims in mind. Plaintiffs timely filed their motion to amend in accordance with this date.

ARGUMENT

I. None of Plaintiffs' Proposed Amendments are Preempted by the MDA Under Controlling Precedent.

In their opposition to Plaintiffs' Motion to Amend, Defendants argued that Plaintiffs' Chapter 93A claims should be denied because they are preempted by the MDA. This Court's Order denying Plaintiffs' proposed amendments cited as authority for its decision one of the cases Defendants used in support of this position, *Talbott v. C.R. Bard*, 865 F. Supp. 37 (D.

Mass. 1994), *aff'd* 63 F.3d 25 (1st Cir. 1995). However, *Talbott* no longer represents controlling First Circuit law regarding preemption.

The United States Supreme Court's decision in *Medtronic v. Lohr* drastically changed the law of preemption under the MDA, effectively overruling previous First Circuit precedent, including most portions of the cases cited by Defendants, which provided blanket preemption of state statutory and common law relating to class III medical devices. Instead of embracing blanket preemption, *Medtronic* held that preemption under Section 360k(a) may "occur only where a particular state requirement threatens to interfere with a specific federal interest." *Medtronic v. Lohr*, 518 U.S. 470, 500 (1996). The Court went on to state that a party claiming preemption must perform a detailed, factual "comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." *Id.* Importantly, where the federal requirements "reflect important but entirely generic concerns about device regulation generally," and the state law requirements "were not specifically developed 'with respect to' medical devices," the Court held that the state requirements would not be preempted. *Id.* at 501.

As Defendants conceded in their Opposition, and as the District Court of Massachusetts has already determined relying upon the change mandated by *Medtronic*, state common law claims are no longer preempted by the MDA, including Plaintiffs' claims relating to negligence and warranty, absent a specific showing as described in *Medtronic*. *Comeau v. Heller*, 945 F. Supp. 7, 12 (D. Mass. 1996); Def. Br. at 5 n.2. This is also true where the device has only undergone the 510(k) premarket notification process as a device "substantially equivalent" to other products on the market. In such circumstances, the District Court of Massachusetts,

relying on the *Medtronic* decision, has held that "the 510(k) 'substantial equivalence' process does *not* impose specific federal requirements on the design of a medical device and therefore does not preempt state law claims of defective design or manufacture." *Lake v. TPLC*, 1 F. Supp. 2d 84, 86 (D. Mass. 1998) (emphasis in original). Plaintiffs filed their motion to amend at the outset of discovery, therefore Plaintiffs do not know what federal requirements were met by Zimmer products other than the Centralign, and Defendants have not made any showing, much less the detailed factual comparison required under *Medtronic*, that any federal requirements would impose any specific requirements on the devices at issue. Based on *Medtronic* and the District Court of Massachusetts' decisions subsequent to it, Plaintiffs' proposed amendments to its common law claims are not preempted by the MDA and should be allowed.

Not only has *Medtronic* changed the face of preemption with regard to common law claims, it has ended automatic preemption of statutory claims as well, contrary to Defendants' assertions. In 1999, three years after the *Medtronic* decision, the District Court of Massachusetts specifically addressed whether Section 360k(a) of the MDA preempted a plaintiff's Chapter 93A claim that the manufacturer of a class III medical device had engaged in unfair and deceptive trade practices. *Haidak v. Collagen Corp.*, 67 F. Supp. 2d 21, 34 (D. Mass. 1999). In *Haidak*, the Court reviewed whether MDA preemption still applied to claims made regarding a class III medical device that had been subjected to the FDA's rigorous PMA approval process. *Id.* at 29. The Court first held that under the MDA and the *Medtronic* decision, "a party claiming preemption still 'must demonstrate that "there is a conflict between the state and federal regulations of the medical devices which threatens to interfere with a specific federal interest."'" *Id.* at 33 (citations omitted). Then, specifically addressing the plaintiff's Chapter 93A claims, the Court held that "Congress has spoken with unmistakable clarity that Section 360k(a) 'does not

preempt State or local requirements of general applicability where the purpose of the requirement relates... to unfair trade practices in which the requirements are not limited to devices.'" *Id.* at 34. Based on these determinations, the Court held that the plaintiff's Chapter 93A claim was not preempted by the MDA. *Id.* Under this same analysis, Plaintiffs' Chapter 93A claims should also be allowed to proceed.

In accordance with *Medtronic* and the District Court of Massachusetts' decisions based upon it, neither Plaintiffs' common law nor Chapter 93A claims are preempted under the MDA. Neither the common law nor statutory claims proposed by Plaintiffs were specifically developed "with respect to" medical devices, which *Medtronic* requires for such claims to be preempted. Finally, Defendants have not made any showing, as *Medtronic* requires, of a specific conflict between federal law and the state requirements upon which Plaintiffs' claims rely, to justify their claim of preemption and, as the *Haidak* decision observes, no such conflict exists. Accordingly, Plaintiffs' proposed amendments are not futile and should be allowed.

Finally, while the Court's Order did not address Defendants' argument that Plaintiffs' Motion to Amend should be denied because it is unduly delayed, Plaintiffs bring to the Court's attention that this argument is also directly in conflict with the law of this Circuit. Defendants relied solely on a Kansas decision to claim that undue delay is sufficient to bar Plaintiffs' amendments without any showing of prejudice to the Defendants. Def. Br. at 6 (citing *Deghand v. Wal-Mart Stores, Inc.*, 904 F. Supp. 1218, 1221 (D. Kan. 1995)). In addition to the fact that the delay in *Deghand* was focused upon a violation of the court's scheduling order, an issue not present here, *Deghand* does not represent the law of the First Circuit. Instead, this Circuit has held that a motion to amend should not be denied "solely on the basis of delay." *Greenberg v. Mynczywor*, 667 F. Supp. 901, 905 (D.N.H. 1987). Instead, "a district court must consider

prejudice to the opposing party." *Id.* Thus a court "may not deny an amendment solely because of delay and without consideration of the prejudice to the opposing party." *Tingley Systems, Inc. v. CSC Consulting, Inc.*, 152 F. Supp. 2d 95, 116 (D. Mass. 2001) (citing *Hayes v. New England Millwork Distributors, Inc.*, 602 F.2d 15, 19 (1st Cir. 1979)). Plaintiffs' amendments are not unduly delayed because they are offered at the outset of discovery in accordance with this Court's Scheduling Order, giving Defendants ample time and ability to fully explore their bases. More importantly, Defendants have not shown, or even argued, that they will suffer any prejudice if the amendments are allowed. Defendants' argument that Plaintiffs' proposed amendments are unduly delayed is incorrect and unsupported by any showing of prejudice, and Plaintiffs' amendments should be allowed.

II. In the Alternative, Plaintiffs Request Certification of the Court's September 6, 2004 Order for Interlocutory Appeal to Determine the Key Issue of Preemption.

In the alternative to Plaintiffs' Motion for Reconsideration, Plaintiffs respectfully move the Court for an order pursuant to 28 U.S.C. § 1292(b) certifying this Court's September 6, 2004 Order for interlocutory appeal and staying this case pending the outcome of the appeal. Certification is proper where: (1) the order to be appealed involves a controlling question of law; (2) there is substantial ground for difference of opinion on that question of law; and (3) an immediate appeal from the order may materially advance the ultimate termination of the litigation. 28 U.S.C. § 1292(b); *In re Lupron Marketing and Sales Practices Litig.*, 313 F. Supp. 2d 8, 9 (D. Mass. 2004). All of these factors are met here, and Plaintiffs therefore respectfully request that this Court certify its order for interlocutory appeal.

For the purposes of certification under 28 U.S.C. § 1292, a controlling question of law is one that "has the potential of substantially accelerating disposition of the litigation." 19 Moore's Federal Practice ¶ 203.31[3] (3d ed. 1997). The "resolution of an issue need not necessarily

terminate an action in order to be 'controlling.'" *Klinghoffer v. S.N.C. Achille Lauro*, 921 F.2d 21, 24 (2d Cir. 1990). Whether Plaintiffs' proposed additional claims of negligence and warranty for products other than the Centralign, or their proposed claim under Chapter 93A, would be preempted by the MDA is a controlling question of law. Preemption is a substantial and definitive issue, which if found will completely preclude a party from even raising any claims as to which preemption has been determined. Deciding this issue at this point is therefore crucial, as an unreviewed ruling may expose the parties to substantial expense and delay if after trial an appellate court were to find that Plaintiffs' additional claims relating to negligence, warranty, and Chapter 93A were not preempted by the MDA. Other courts have therefore found that issues of preemption are appropriate for interlocutory appeal as they present controlling questions of law. *Taylor v. PPG Industries, Inc.*, 256 F.3d 1315, 1316 (Fed. Cir. 2001); *District 65 Retirement Trust v. Prudential Securities, Inc.*, 925 F. Supp. 1551, 1571 (N.D. Ga. 1996).

Whether Plaintiffs' proposed claims are preempted is also an issue as to which there is a substantial ground for difference of opinion. This Court's September 6 Order held that all of Plaintiffs' proposed amendments, both common law and statutory claims, were preempted by the MDA, relying upon the *Talbott v. C.R. Bard* decision cited by Defendants. However, as Plaintiffs have discussed in detail above in Section I, *Talbott's* call for complete preemption of state law claims related to medical devices has been effectively overruled by *Medtronic v. Lohr*; and multiple decisions in the First Circuit and the District of Massachusetts have followed *Medtronic's* reasoning and specifically applied it to the claims Plaintiffs present. Therefore, this Court's decision has created an issue as to which there is a substantial ground for difference of opinion, which would be appropriate to certify for interlocutory review.

Finally, certification of this Court's September 6 Order will materially advance the ultimate termination of this litigation. As other federal courts have noted, and as would be true here, "protracted and expensive litigation may needlessly result" if the Court's rulings are "ultimately overturned." *Consumer Prods. Safety Comm'n v. Anaconda Co.*, 445 F. Supp. 498, 501 (D.D.C. 1977). Should this issue be held until after trial, and should a court on appeal find that Plaintiffs' proposed additional claims relating to other products and Chapter 93A are not preempted, an entirely new trial would become necessary to litigate these claims. Such a substantial delay will be efficiently avoided by certification of the important issue of preemption for interlocutory appeal and a stay of the current proceedings pending resolution of the appeal, as these claims can then be easily and seamlessly integrated into the current litigation should the Court of Appeals find that they are not preempted.

CONCLUSION

Defendants have misstated First Circuit law in an attempt to argue that Plaintiffs' motion to amend is preempted and untimely. First Circuit law does not support either of these propositions. Plaintiffs' proposed additions to its common law claims and its proposed claim under Chapter 93A are not preempted according to the District Court of Massachusetts' post-*Medtronic* decisions, and Defendants have not presented any evidence or argument that Plaintiffs' proposed claims interfere with a specific federal regulation, as required by *Medtronic*. Further, Plaintiffs' amendments are timely, in accordance with this Court's scheduling Order, and Defendants have not argued that any prejudice would result from their allowance. Accordingly, Plaintiffs respectfully request that this Court reconsider its September 6, 2004 Order relying upon Defendants' misstatements of controlling law. In the alternative, because of the controlling questions of law and substantial differences of opinion that the issue of

preemption raises, Plaintiffs respectfully request that this Court certify its September 6 Order for interlocutory appeal and stay this case pending resolution of the appeal to efficiently and materially advance this litigation.

Dated this 20th day of September, 2004.

Respectfully submitted,

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

Dean Langford and Nancy Langford, husband and wife, Plaintiffs, v. Zimmer, Inc. and Zimmer Holdings, Inc., Defendants.	**Case No: 03-12245-RCL** **AFFIDAVIT OF ELIZABETH A. MAKI IN ACCORDANCE WITH LOCAL RULE 7.1**

COUNTY OF HENNEPIN)
) ss.
STATE OF MINNESOTA)

Elizabeth A. Maki, one of the attorneys for plaintiffs in the above case, being first duly sworn upon oath, states and alleges as follows:

1. On September 20, 2004, I spoke with Albert Dahm, attorney for Defendants, and discussed with him Plaintiffs' intention to bring this Motion. Mr. Dahm acknowledged Plaintiffs' intent to bring the Motion.

FURTHER YOUR AFFIANT SAYETH NOT.

Elizabeth A. Maki

Subscribed and sworn to before
me this 20th day of September, 2004.

Notary Public

PATRICIA A. METCALF
NOTARY PUBLIC-MINNESOTA
My Commission Expires Jan. 31, 2005

CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of September, 2004, I electronically filed the foregoing Memorandum of Law in Support of Plaintiffs' Motion for Reconsideration of Order Denying Plaintiffs' Motion to Amend or in the Alternative for Certification pursuant to 28 U.S.C. § 1292 (b) with the Clerk of Court using the CM/ECF system, which will send notification of such filing to the following:

Edgar B. Hatrick
Day, Berry & Howard LLP
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I further hereby certify that on this 20th day of September, 2004, a copy of the foregoing Memorandum of Law in Support of Plaintiffs' Motion for Reconsideration of Order Denying Plaintiffs' Motion to Amend or in the Alternative for Certification pursuant to 28 U.S.C. § 1292 (b) will be sent to the following via First Class Mail:

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